



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------------|
| 10/580,190 | 05/23/2006 | Ezio Bombardelli | 2503-1215 | 1808 |
| 466 7590 01/02/2008 YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202 | | | EXAMINER MI, QIUWEN | |
| | | | ART UNIT 1655 | PAPER NUMBER |
| | | | MAIL DATE 01/02/2008 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/580,190 | BOMBARDELLI, EZIO | |
| | Examiner | Art Unit | |
| | Qiuwen Mi | 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 6-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 6-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment in the reply filed on 11/8/07 is acknowledged. Any rejection that is not reiterated is hereby withdrawn.

Claims Pending

Claims 16-23 are newly submitted. Claims 3-5 are cancelled. Claims 1, 2, and 6-23 are pending. Claims 1, 2, and 6-23 are examined on the merits.

Claim Objections

Claim 15 is objected to because of the following informalities: Claim 15 recites "for the treatment of the affections of oral activity...", and Applicant is suggested to change the misspelling "affections"; and change it to "infection". Appropriate correction is required.

Claim Rejections –35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 15, and 17 are rejected under 35 USC § 102 (b) as being anticipated by Korneyev (US 6,576,269), as evidenced by Zulli et al (US 2002/0131942)* and Ghosal (US 6,224,906)*.

Korneyev teaches a composition comprising grape seed and St. John's Wort (the same as *Hypericum perforatum*, see Abstract).

As evidenced by Zulli et al, grape seed contains procyanidins [0007].

As evidenced by Ghosal, St. John's Wort extract (the same as *Hypericum perforatum*, col 1, lines 10-15) contains phloroglucinols and procyanidins (cols 2&3, Table 1).

Therefore, the reference is deemed to anticipate the instant claim above.

Claims 1, 6, 15, and 17 are rejected under 35 USC § 102 (b) as being anticipated by Yaloveny Agric Ind (SU 1373398A), as evidenced by Nieuwenhuizen et al (US 2003/0064937)*, and Cooper et al (US 6,379,720)*.

Yaloveny Agric Ind teaches a composition comprising grapes and extract of hops (see Abstract)

As evidenced by Nieuwenhuizen et al (US 2003/0064937), grape contains procyanidins [0023, 0077].

As evidenced by Cooper et al, hops (the same as *Humulus lupulus*, col 1, lines 50-55) extract contains alpha acids (phloroglucinols), represented by humulone and its congeners (cohumulone, admululone) and beta acids, represented by lupulone and its congeners (colupulone, adlupulone) (col 1, lines 50-58).

Therefore, the reference is deemed to anticipate the instant claim above.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6, 9, 10, 15, 16, 17, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korneyev (US 6,576,269), as evidenced by Zulli et al (US 2002/0131942)* and Ghosal (US 6,224,906)*.

Korneyev teaches a composition comprising grape seed and St. John's Wort (the same as *Hypericus perforatum*, see Abstract).

As evidenced by Zulli et al, grape seed contains procyanidins [0007].

As evidenced by Ghosal, St. John's Wort extract (the same as *Hypericum perforatum*, col 1, lines 10-15) contains phloroglucinols and procyanidins (cols 2&3, Table 1).

Korneyev does not teach the claimed amount of the components.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the invention of Korneyev since the composition of Korneyev yielded beneficial results in for treating open skin lesions, one of ordinary skill in the art would have been motivated to make the modifications. The result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of the components within the

composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 1, 2, 7, 8, 15, 16, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yaloveny Agric Ind (SU 1373398A), as evidenced by Nieuwenhuizen et al (US 2003/0064937)*, and Cooper et al (US 6,379,720)*.

Yaloveny Agric Ind teaches a composition comprising grapes and extract of hops (see Abstract)

As evidenced by Nieuwenhuizen et al (US 2003/0064937), grape contains procyanidins [0023, 0077].

As evidenced by Cooper et al, hops (the same as *Humulus lupulus*, col 1, lines 50-55) extract contains alpha acids (phloroglucinols), represented by humulone and its congeners (cohumulone, admululone) and beta acids, represented by lupulone and its congeners (colupulone, adlupulone) (col 1, lines 50-58).

Yaloveny Agric Ind does not teach the claimed amount of the components in the composition.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the invention of Yaloveny Agric Ind since the composition of Yaloveny Agric Ind yielded beneficial results in food industry, one of ordinary skill in the art would have been motivated to make the modifications. The result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of the components within the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 1, 2, and 6-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Walker et al (US 5,474,774), Imaoka et al (JP 406179609), Barney et al (US 5,370,863), Van den Berghe (US 6,284,289), and Zou (CN 1421240), as evidenced by Gorenbein et al (US 5,955,102)*, Nieuwenhuizen et al (US 2003/0064937)*, Cooper et al (US 6,379,720)*, Ghosal (US 6,224,906)*, and Giovanni et al (Oligomeric acylphloroglucinols from myrtle (*Myrtle communis*), Journal of Natural Products, 65 (3): 334-8, 2002)*.

Walker et al teach a composition for inhibiting the adhesion of *E. coli* bacteria to surfaces in a mammalian oral cavity (thus administering to a patient) (claim 1). Walker et al also

teach that the invention comprises an extract made from plant material of plant species of the genus *Vaccinium*, and which is significantly enriched for an activity that interferes with adhesion of bacterial cells to surfaces (col 1, lines 42-46). Walker et al further teach that *V. myrtillis* (bilberry), etc are useful species (col 1, lines 63-67).

As evidenced by Gorenbein et al, bilberry extract (the same as *Vaccinium myrtillus*, col 3, lines 10-15) contains anthocyanoside.

Imaoka et al teach a composition with high antibacterial activity on oral bacteria (thus administering to a patient) comprising grape extract.

As evidenced by Nieuwenhuizen et al (US 2003/0064937), grape contains procyanidins [0023, 0077].

Barney et al teach a composition for inhibiting undesirable gram positive microorganisms in the oral cavity bacteria proliferation (thus administering to a patient) comprising hops acids (col 1, lines 5-10).

As evidenced by Cooper et al, hops (the same as *Humulus lupulus*, col 1, lines 50-55) extract contains alpha acids (phloroglucinols), represented by humulone and its congeners (cohumulone, adhumulone) and beta acids, represented by lupulone and its congeners (colupulone, adlupulone) (col 1, lines 50-58).

Van den Berghe teaches a composition for treating cold sores (infection in oral cavity) (thus administering to a patient) comprising *Myrtus communis* and *Hypericum perforatum* (col 4, lines 14-22).

As evidenced by Ghosal, 'St. John's Wort extract (the same as *Hypericum perforatum*, col 1, lines 10-15) contains phloroglucinols and procyanidins (cols 2&3, Table 1).

As evidenced by Giovanni et al, *Myrtus communis* contains phloroglucinols (see Abstract).

Zou teaches a composition for treating sore and swelling throat, acute pharyngitis, and acute laryngitis (oral cavity infection) (thus administering to a patient) comprising mint oil (see Abstract).

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ...[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.).

In the instant case, all of the above-listed ingredients were known for oral cavity infection. Thus, one of ordinary skill in the art would have had a reasonable expectation that the

combination of these compounds would have been additively beneficial in treating any inflammatory condition including brain inflammation in multiple sclerosis patients.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for oral cavity infection. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the amounts of each constituent as in the claims, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions of Walker et al, Imaoka et al, Barney et al, Van den Berghe, and Zou since all of them teach compositions for oral cavity infection individually in the art. Since all the compositions yielded beneficial results in for oral cavity infection, one of ordinary skill in the art would have been motivated to make the modifications. The result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of the components within the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Claim 11 is a product-by-process claim. It is deemed that the product disclosed by Van den Berghe is not materially differently from the claimed *Myrtus communis* extract, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

*This reference is cited merely to relay an intrinsic property and is not used in the basis for rejection *per se*.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Qiuwen Mi



MICHAEL MELLER
PRIMARY EXAMINER